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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,401	11/10/2003	Henrik Clausen	04305/100H154-US2	4414

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,401

Applicant(s)

CLAUSEN ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/04, 11/04, 08/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election of Group II (claims 5-8) in the reply filed on 08/17/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-4 and 9-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
2. Claims 5-8 are under consideration in this Office Action

Claim Objections

3. Claims 5-8 are objected to because the claims recite the abbreviation "GalNAc-transferase" without defining it in the claim. Amending the claim to recite "UDP-GalNAc: polypeptide N-acetylgalactosaminyltransferases" as stated in the specification on page 3, lines 13-14, may overcome the objection.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 6 and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
In claim 6 the phrase "amino acid sequences of GalNAc-T1 to T16 set forth in Table III herein" renders the claim vague and indefinite because it is not clear what specific amino acid sequences are referred to. Amending the claim to recite the specific SEQ ID NO identifier may overcome the rejection. Claim 7 is also rejected because it does not correct the defect of claim 6.

In claim 7 the phrase "comprising 10-20 amino acid residues of the corresponding GalNAc-transferase" renders the claim vague and indefinite since it is not certain what specific

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amino acid sequence is being referred to. Amending the claim to recite the specific SEQ ID NO identifier may overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of isolated lectin polypeptides of any amino acid sequence and structure consisting of any truncated mammalian GalNAc-transferase polypeptide comprising any domain selected from the group consisting of the lectin domain of any mammalian polypeptide GalNAc-transferase, any lectin-functional variant and fragments thereof. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences and biological functions. Furthermore, each genus is highly variable because a significant number of structural and biological differences between genus members exist.

The specification discloses in Example 3 HIS-tagged truncated GalNAc-T2 and -T4 lectins consisting of the SEQ ID NO: 99 and SEQ ID NO: 103, respectively. However, the specification does not describe and define any structural features, amino acid sequences, and biological functions that are commonly possessed by members of the genus. The claims as written do not recite a particular structure to function relationship. The specification fails to provide a written description of representative members of the claimed genus. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of each genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of

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genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of isolated lectin polypeptides of any amino acid sequence and structure consisting of any truncated mammalian GalNAc-transferase polypeptide comprising any domain selected from the group consisting of the lectin domain of any mammalian polypeptide GalNAc-transferase, any lectin-functional variant and fragments thereof. Claims 6-8 which depend from claim 5 are also rejected because they do not correct the defects of claim 5.

8. Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for HIS-tagged truncated GalNac-T2 and -T4 lectins consisting of the SEQ ID NO: 99 and SEQ ID NO: 103, respectively; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass isolated lectin polypeptides of any amino acid sequence and structure consisting of any truncated mammalian GalNAc-transferase polypeptide comprising any domain selected from the group consisting of the lectin domain of any mammalian polypeptide GalNAc-transferase, any lectin-functional variant and fragments thereof.

The specification provides guidance and examples for HIS-tagged truncated GalNac-T2 and -T4 lectins consisting of the SEQ ID NO: 99 and SEQ ID NO: 103, respectively, as shown in Example 3. However, the specification does not provide guidance, prediction, and working examples for making any other isolated lectin polypeptide as recited in the claims. The specification does not provide guidance, prediction, and working examples showing that

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truncating any GalNAc-transferase such that it does not have the catalytic domain will result in a polypeptide that still has lectin binding activity.

Thus, an undue amount of trial and error experimentation must be preformed to search and screen for any and all mammalian GalNAc-transferase; and determining whether truncating the mammalian GalNAc-transferase will result in the production a polypeptide that retains the ability to bind lectins. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

Conclusion

9. No claims are allowed.

10. The following reference made of record and not relied upon is considered pertinent to applicants' disclosure: Tenno et al. (J Biol Chem. 2002 Dec 6;277(49):47088-96. Epub 2002 Oct 2) teach that the lectin domain of UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase 1 is involved in O-glycosylation of a polypeptide with multiple acceptor sites

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF